REMARKS

Claims 68 – 142 are pending in the instant application. Claims 70 – 77, 79, 81 – 91, 94 – 117, and 120 – 137 have been deemed withdrawn by Examiner as not directed to elected subject matter. New claims 141 and 142 are presented. Therefore, claims 68 – 69, 78, 80, 92 – 93, 118 – 119, and 138 – 142 will be pending upon entry of the amendments presented herein.

Claims 68 – 69, 92 – 93, 118 – 119, 138 – 139, and 140 have been amended to make editorial changes and to recite more fully the invention, *e.g.*, in claim 140, the word "uracil," an obvious clerical error, has been corrected to "β-amino anionic compound." Support for new claims 141 and 142, and indeed *all* of the pending claims, documented herein, below. No new matter has been added. Attached hereto as an Appendix is a marked-up version of the changes made to the claims by the current amendments.

Amendment of claims is not to be construed as an acquiescence to any of the objections/rejections set forth in the instant Office Action, and was done solely to expedite prosecution of the application. Applicants reserve the right to pursue the claims as originally filed, or similar claims, in this or one or more subsequent patent applications.

Written Support in Specification as Filed for Pending Claims

The present invention relates to anti-epileptogenic agents. Amended claims 68 and 69 are directed to a specific class of anti-epileptogenic agents. Support for amended claims 68 and 69 may be found in the specification, for example, at p. 3, ll. 2 – 6:

> *In preferred embodiments, the anti-epileptogenic agent is a β-amino anionic compound, in which an anionic moiety is selected from the group consisting of carboxylate, . . .*

The specification, for example at p. 14, ll. 21 – 31, further defines the term β-amino anionic compound:

> *The term "β-amino anionic compound," as used herein, refers to a compound having an amino group (e.g., -NR^aR^b, in which R^a and R^b are each*

independently hydrogen, alkyl, alkenyl, alkynyl, cycloalkyl, aryl, alkylcarbonyl, arylcarbonyl, alkoxycarbonyl, or aryloxycarbonyl, or R^a *and* R^b*, taken together with the nitrogen atom to which they are attached, form a cyclic moiety having from 3 to 8 atoms in the ring) separated from an anionic group by a two-carbon spacer unit. Thus, for example, a β-amino anionic compound can be represented by the formula A-CHR'CHR'-*NR^aR^b*, . . .*

Exemplary substituents of β-amino anionic compounds of the invention are recited in the specification, for example at p. 4, ll. 18 – 20:

[the substituent] is alkyl, alkenyl, alkynyl, cycloalkyl, aryl, alkoxy, aryloxy, alkylcarbonyl, arylcarbonyl, alkoxycarbonyl, aryloxycarbonyl, amino, hydroxy, cyano, nitro, thiol, thiolalkyl, halogen, carboxyl, alkoxycarbonyloxy, aryloxycarbonyloxy or aminocarbonyl . . .

The specification further states that the substituent of a β-amino anionic compound of the invention may also be any "substituent of an alkyl group" (*see* p. 14, l.28), and exemplary substituents of an alkyl group are recited in the specification at p. 15, ll.16 – 23:

substituents can include, for example, halogen, hydroxyl, alkylcarbonyloxy, arylcarbonyloxy, alkoxycarbonyloxy, aryloxycarbonyloxy, carboxylate, alkylcarbonyl, alkoxycarbonyl, aminocarbonyl, alkylthiocarbonyl, alkoxyl, phosphate, phosphonato, phosphinato, cyano, amino (including alkyl amino, dialkylamino, arylamino, diarylamino, and alkylarylamino), acylamino (including alkylcarbonylamino, arylcarbonylamino, carbamoyl and ureido), amidino, imino, sulfhydryl, alkylthio, arylthio, thiocarboxylate, sulfates, sulfonato, sulfamoyl, sulfonamido, nitro, trifluoromethyl, cyano, azido, heterocyclyl, or an aromatic or heteroaromatic moiety . . .

The subject matter of claims 68 and 69 may therefore be found in the specification of the parent application as filed and these claims are entitled to at least the filing date of the parent application.

Claims 78 and 80 further stipulate that the aryl groups of the preceding claims may be substituted. As used in the specification, unless otherwise specified, the term "aryl" includes substituted or unsubstituted aryl groups. Indeed, the specification states at p.15, l.34 *et seq.*:

> *The aromatic ring can be substituted at one or more ring positions with such substituents as described above, as for example, halogen, hydroxyl, alkylcarbonyloxy, arylcarbonyloxy, alkoxycarbonyloxy, aryloxycarbonyloxy, carboxylate, alkylcarbonyl, alkoxycarbonyl, aminocarbonyl, alkylthiocarbonyl, alkoxyl, phosphate, phosphonato, phosphinato, cyano, amino (including alkyl amino, dialkylamino, arylamino, diarylamino, and alkylarylamino), acylamino (including alkylcarbonylamino, arylcarbonylamino, carbamoyl and ureido), amidino, imino, sulfhydryl, alkylthio, arylthio, thiocarboxylate, sulfates, sulfonato, sulfamoyl, sulfonamido, nitro, trifluoromethyl, cyano, azido, heterocyclyl, or an aromatic or heteroaromatic moiety.*

Claims 78 and 80 therefore are supported by the specification of the parent application as filed and these claims are entitled to at least the filing date of the parent application.

The present invention is likewise directed to β-amino anionic compounds which are β-substituted β-alanines as in amended claim 92. For example, the specification starting at p. 47 contains an entire section entitled "Synthesis of β-Substituted-β-Alanines." Because the subject matter of claim 92 is found in the specification of the parent application as filed, this claim is entitled to at least the filing date of the parent application.

Likewise, as noted above in the discussion of claims 68 and 69 above, the specification (at p. 4, ll. 18 – 20) states that substituents of β-amino anionic compounds include alkyl, cycloalkyl, and aryl groups. Therefore, claim 93 finds support in the specification of the parent application as filed, and this claim is entitled to at least the filing date of the parent application.

Amended claims 118 and 119 merely recite the compounds which are in Tables 1 and 2 of the specification of the parent application as filed, and therefore are entitled to at least the filing date of the parent application. (Note that Table 1 was amended in the preliminary amendment filed with the present application, for clarity, to also present the yield data from Table 2. The first appearance of "3-Methylphenyl" in Table 1 as filed was corrected for consistency with the corresponding entry in Table 2, page 55, second row, *i.e.*, 3-(4-methylphenoxy)-phenyl. Nevertheless, all of the compounds recited in amended claims 118 and 119 are found in the specification of the parent application as filed.)

Amended claim 138 and new claim 142 are directed to similar chemical compounds as claims 68 and 69, but are directed to a method of "treating a convulsive disorder" rather than "inhibiting epileptogenesis." Note that the first sentence of the "Summary of the Invention" at p. 2, ll.23 – 24 of the specification reads, "[t]his invention relates to methods and compounds useful for the treatment and/or prevention of convulsive disorders . . ." Claims 138 and 142 are therefore supported by the specification of the parent application as filed.

The specification abounds with dozens of examples of substituted β-alanine compounds, and therefore claim 139 directed to such substituted β-alanine compounds is clearly supported by the specification as filed. Likewise, the specification teaches that α-substituted compounds may be used in the methods of the invention, and a working example of such a compound is provided in the specification at p. 69, l.26 *et seq.*

Claims 140 and 141 further stipulate that the β-alanine compound may be α-substituted (*see, e.g.*, the formula at p.4, l.15), or β-substituted (see discussion above in the discussion of claim 92, regarding the specification starting at p. 47 which contains an entire section directed to the β-substituted-β-alanines). Similarly, claims 140 and 141 are directed to the multiply-substituted alanines described in the specification at p.20, ll.7 – 11:

> *The method includes the step of administering to a subject in need thereof an effective amount of a compound selected from the group consisting of α, α-disubstituted β-alanines, α, β-disubstituted β-alanines, β, β-disubstituted β-alanines, α, β, α-trisubstituted β-alanines, α, β, β-trisubstituted β-alanines, and*

α, α, β, β-tetrasubstituted β-alanines; or a pharmaceutically acceptable salt thereof. . .

Claims 140 and 141 are therefore supported by the specification of the parent application as filed. Indeed, all of the currently pending claims are supported by the specification of the parent application as filed, and are entitled *at least* to the filing date of the parent application, *i.e.*, U.S. 09/041,371, filed March 11, 1998, or the priority applications U.S. 60/041,140, filed March 12, 1997 and U.S. 60/073,536, filed February 3, 1998.

Inventorship

Please note that the first-named inventor of the present application is Donald **F.** Weaver, and *not* Donald **E.** Weaver. Although the Declaration/Power of Attorney recites the middle initial of the name of this inventor erroneously, Inventor Weaver signed the Declaration/Power of Attorney using the middle initial "F." Also note that the application papers were filed in the name of Donald F. Weaver. In this regard, a Request for a corrected Filing Receipt has been submitted simultaneously to the Office of Initial Patent Examination, and a copy of the Request is enclosed with this Amendment and Response.

Claim Rejections – 35 U.S.C. § 112

Rejection of Claims under 35 U.S.C. § 112, first paragraph

Claims 68 – 69, 78, 80, 92, 93, and 138 – 140 are rejected under 35 U.S.C. § 112, first paragraph, "as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention."

In particular, the Office Action states that the "claims are drawn to a method of use of substituted β-alanine compounds represented by a formula (as shown in claim 68) wherein both the α carbon and the β carbons are disubstituted by R^1 which is defined to be H, alkyl, aryl, etc. The specification however does not adequately support the instantly recited generic group of

compounds. First, the formula of claims 68 and 138 added by preliminary amendment was not found any where in the specification and there is no generic support for the instantly recited structural formula having the diverse combinations of the substituents."

The presently amended claims no longer refer to the formula objected to in the Office Action, and therefore reconsideration is requested.

The Office Action further states that the specification provides an example of "a β-amino anionic compound represented by the formula A-CHR'CHR'-NR_aR_b wherein R' is H or alkyl. However, there is no disclosure of disubstitution at both the α and β carbons."

Applicants assert that the formula "A-CHR'CHR'-NR_aR_b" clearly indicates that both the α- and β-position may be substituted independently, and therefore simultaneously. Additionally, Applicants direct Examiner to the specification at p.20, ll.7 – 11, which specifically states that α,β-disubstituted β-alanines are within the scope of the invention. Therefore, the disubstituted compounds are adequately described in the specification, and reconsideration of this rejection is requested.

Additionally, the Office Action states that the specification teaches that the compounds used in the method may be selected from α,α,β,β-tetrasubstituted β-alanines, but that the substituents of such a compound are not specified.

Applicants assert that one skilled in the art would appreciate that the substituents recited in the specification for the α-substituted β-alanines at p. 4, ll. 18 – 20 would analogously apply to the other substituted β-alanines described in the specification. Furthermore, the specification teaches (at p.14, l.28) that any β-amino anionic compound, which an α,α,β,β-tetrasubstituted β-alanine surely is, may be substituted with any substituent which an alkyl group may have. Accordingly, the substituents of an α,α,β,β-tetrasubstituted β-alanine are inherently described.

The Office Action also states that "in the definition of A, it is recited 'a prodrug form thereof', however, no adequate support for the instant recitation is found. As the claims no longer refer to "prodrugs," reconsideration of this rejection is requested.

Rejection of Claims under 35 U.S.C. § 112, second paragraph

In rejecting claim 68, the Office Action states that regarding the phrase "a substituted β-alanine compound," A is defined to be "an anionic group at physiological pH" which "includes sulfate, sulfonate, etc." However, according to the Office Action "a β-alanine compound must have a carboxylate group at the 1-position and an amino group at the 2-position. When A is other than a carboxylate group, the compound is no longer a β-alanine compound and therefore, it is not clear how the claimed group of compounds are referred to as β-alanine compounds."

The present claims have been amended to refer to "β-amino anionic compounds" and a description of such compounds may be found in the specification. The objections raised in the Office Action respecting "β-alanine compounds" are therefore believed to be moot, and reconsideration is therefore requested.

In rejecting claims 78 and 80, the Office Action states that the recitation "said aryl or said aryloxy group is substituted" lacks sufficient antecedent basis in claims 69 or 68 on which the claims depend because the base claims do not recite that any of the groups may be further substituted.

Likewise, claims 118 and 119 are rejected in the instant Office Action because they "recite several substituted phenyl groups in the definition of R, see e.g., 3-(4-chlorophenoxy)phenyl, etc. [for which there] is insufficient antecedent basis for these substituted phenyl groups in the base claims 68 or 69 [because the] independent claim[s] does not recite that aryl group is further substituted."

As noted above, the term "aryl" (and the term "phenyl") is used in the specification as well as the claims to refer to an unsubstituted or substituted aryl group (unless otherwise specified). Therefore, sufficient antecedent bases exists and reconsideration is requested.

Claim 139 is rejected in the Office Action because the "recitation 'or a derivative, analog' is not understood [because the] claim already recites 'substituted or unsubstituted β-alanine compound' and therefore, it is not clear what else is intended by the instant recitation."

In view of Applicants' amendments to claim 139, reconsideration of this rejection is requested.

Claim 140 recites "said uracil" which the Office Action indicates lacks sufficient antecedent basis in claim 139 or 138 on which claim 140 is dependent. The word "uracil" in the claim was an inadvertent error, and it has been corrected to "β-amino anionic compound." Therefore, reconsideration is requested.

Claim Rejections – 35 U.S.C. § 102(b)

The instant Office Action rejects the claims under 35 U.S.C. § 102(b) as being anticipated by Weaver, *et al.*, WO 98/400,535, published September 17, 1998, and filed March 12, 1997. This reference allegedly constitutes prior art because, according to the Office Action, the pending claims do not satisfy the requirements of U.S.C. § 112, first paragraph and therefore are not entitled to the priority dates claimed.

This PCT publication is the corresponding international patent application of the present divisional application's parent application (U.S. application no 09/041,371, filed March 11, 1998, *i.e.*, before the publication date of the PCT application, and one day before the application date of the PCT). In view of the amendments and arguments presented herein, Applicants submit that the claims as amended are adequately supported by the specification of the parent application as filed and accordingly the PCT application is not citable against the present application. Applicants respectfully request that the present rejection be withdrawn.